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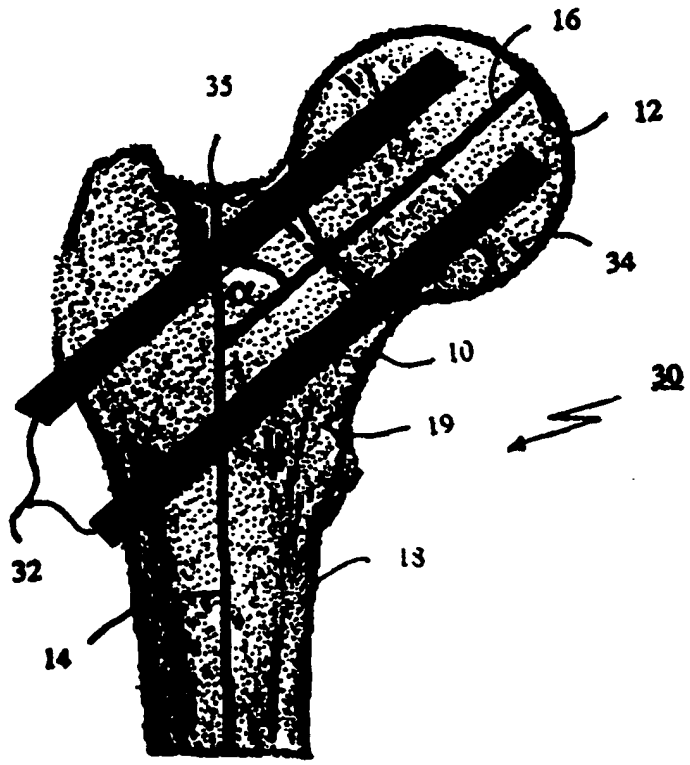
(54) Title: METHOD AND ARRANGEMENT FOR TAKING UP APERTURES

(57) Abstract

The present invention is comprised of a method for determining, in three dimensions, where to position fixating means (32) in bone structure fractures (30) by pre–surgery analysis of at least one anteroposterior and one lateral digitized radiograph of a fracture. The method is applied to control arrangements (100, 140, 150, 200) with a tool for perforating bones in the correct direction in order to accomplish a best possible healing of a fractured bone structure (30), thereby determining positions, distances, X–ray distorsion etc.



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Method and arrangement for taking up apertures

Technical field

The present invention pertains to a method for aligning an arrangement for marking of directions for perforating together with a position determining arrangement, attached to a machine with a movable arm, in bone structures at surgery, and to said arrangements.

Background art

Present methods regarding, for example, hip fracture surgery involves a great deal of craftsmanship. A patient with an injured leg is placed supine on a fracture table and a reduction maneuver is carried out. The foot of an injured leg is firmly fixed in a specially built shoe. Traction and rotation are applied until the fracture is reduced.

A fixation of an injured leg is normally so firm that no movement will take place unless a substantial force is applied to the leg. A mobile X-ray apparatus, a "C-arm", with two perpendicular radiographs, the anteroposterior (AP) and the lateral (Lat) projections, checks quality of reduction. The result of a reduction can only be judged through said at least two radiographs, and no correction for variations in hip rotation is possible.

Screws are inserted in order to fixate the fractured bone parts. The screws are introduced by a hand-held drill which opens up guide holes for the screws, whereby a surgeon has to judge the position of the drill from said two perpendicular radiographs and manually adjust the position of the drill in three dimensions, which is a very difficult task.

Unfortunately, the insertion of screws very often has to be repeated. Repeated trials of insertion destroy the bone structure in the femoral neck.

To be able to check the quality after a performed hip fracture surgery a method was developed for determining the post surgery position of a fixating means. It was introduced by the inventor of the present invention in his thesis "Internal Fixation of Femoral Neck Fractures", Stockholm 1993, ISBN 91-628-0804-4. Nevertheless, the method has only been used for post-surgery quality checks and scientific statistics, and it has not occurred to or been obvious to any person skilled in the art to modify the method so it can be used in determining how and where to drill in a femoral bone fracture in order to attach fixating means and facilitate healing of said fracture in a best possible way.

Today, orthopedic surgery has promulgated towards sophisticated hi-tech implants being manually inserted through in-precise techniques. To manually insert implants is a task for a highly skilled orthopedic surgeon with, for example, 10 years of training in the present medical field.

For diagnosis groups, where a great number of injuries is accumulated, the result of performed surgery is less satisfactory than it could be. Hip fractures belong to such a group, whereby about 18.000 incidents/year occur in Sweden alone, 9.000 cervical and 9.000 pertrochanteric, to a cost of approximately SEK 1.4 billions.

Despite of the more than 100 different fixating methods developed for this kind of fractures, the result of performed surgery is relatively poor. As much as approximately 35 % of all cervical fractures do not heal, and 20% of them have to be re-operated within a time period of 1-2 years. For pertrochanteric fractures the same rates are 10 % and 4 % respectively. Every re-surgery approximately costs SEK 185.000.

It is agreed with among surgeons and other experts that the main reason for the high percentage of re-surgery is an inadequately positioning of the fixating screws, which hold the fracture together during the following healing process, see "Fixation of femoral neck fractures: comparison of the Uppsala and Von Bahr screws." By Rehnberg & Olerud, Acta Orthop Scand 60, 1989, p. 579-584.

Considering the costs of SEK 185.000 for one re-surgery, a decrease in the rate of such surgery with 50 % would gain a save of SEK 160 millions in Sweden a year in surgery costs. A bigger Swedish Hospital would save approximately SEK 8 millions, not to say what is gained in relief for fractured patients.

A known arrangement to support surgery is the so-called ROBODOC® Surgical Assistant System. The ROBODOC® robot is able to precisely prepare a femoral channel for placement of a cementless prosthesis.

Due to the manual surgery technique involved in surgery relating to bone fractures and judgements made from said radiographs in real time during surgery/surgical treatment without any tools for performing analysis, the X-ray radiation will be unnecessary high for patients and personnel serving during surgery.

From US-A-5,603,243 by Finley, an alignment apparatus for aligning X-ray images is known. The apparatus comprises two elongate members in an orthogonal configuration in relation to each other on a supporting framework. Within each member there are four predetermined axes with a plurality of balls mounted on each axis. The balls are preferably of different sizes or are designed to absorb different quantities of X-ray radiation, so that the images of the balls may be recognised individually on an X-ray plate. Since the orientation and spacing of the balls is known, it is possible to determine the

precise position and precise orientation of parts of a patient present within an X-ray image through calculation.

The support frame and the elongated members with axes comprising balls provides a fairly complicated apparatus with a lot of calculations for alignment of X-ray images, thus an alignment method or apparatus of simpler construction would be appreciated.

It would be an advantage therefore, to provide a method and arrangements that can aid a surgeon in preparing and supporting orthopedic surgery. Such a method and arrangements are set forth through attached independent claims. Specific embodiments of the invention are introduced through the attached dependent claims. Hence, the method and arrangements of the present invention and details thereof provides such advantages.

Summary of the disclosed invention

The present invention aims to solve problems related to determining positions, directions and distances in magnified X-ray images for bone structure surgery.

In order to solve said problems, the present invention sets forth a method for aligning a means for marking of directions for perforating together with position determining means, attached to a machine with a movable arm, in bone structures at surgery, comprising the following steps:

attaching a marking pin to said means for marking;

activating said machine and move said means for marking to a defined start position;

assigning said machine a first operation position changing its co-ordinate system so that movement of the marking pin is, approximately, performed within the cross-section of a movable marking pin holder;

aligning said position determining means in relation to said means for marking, said position determining means having at least four round elements;

positioning said position determining means vertical to a reference surface, adjusted so that the marking pin points in a direction, which axis coincides with each round element when the machine moves a specified distance in a square pattern;

placing said position determining means adjacent to the part of the body where the perforation is to be made;

placing an X-ray machine adjusted so that, when radiographs are taken, two of said four round elements cover each other in two orthogonal projection planes;

determining a starting position, whereby said two covered round elements represent the starting position for the machine;

digitizing said radiographs and using the distances between said other non covered round elements in said radiographs, representing the magnification factor, which is calculated and displayed, whereby the magnification factor relates to the movement of the machine arm;

introducing said marking pin through skin and muscles to a position close to the bone structure which is to be perforated;

measuring the distance the marking pin holder has to be moved, thereby giving the machine a second operation position in accordance with the distance the marking pin holder has been moved, whereby the machine arm is able to move around this second position even if the pin and second cylinder is removed, thus all machine movements can take place outside a patients body, but the center of movements will still be close to the bone inside the patients body;

measuring the position of the Marking steel pin, and the lenght to a predetermined marker on said marking pin out off said digitized radiographs, calculating a scale factor for the position of the marker;

marking a desired position for a perforation means in the bone on said digitized radiographs;

comparing a desired position for said perforation means in the bone with the actual position for said marking pin;

making corrections for magnification and scale;

calculating distances and angles that said machine has to move its arm in order to align the marking pin with the perforation position in the bone;

automatic repositioning of the machine in accordance with said calculated distances and angles; and

through said machine, performing a perforation of the bone.

In one embodiment the marking pin is changed to a perforator, held by a similar pin holder, said perforator being suitable for drilling, screwing, pinning, milling, grinding or threading.

In another embodiment, a chosen perforator is advanced, by means of said pin holder, so that it enters through the skin and muscles to a position close to the bone.

In a still further embodiment a checking procedure is performed by marking and outlining the direction and position of the perforator and comparing it with the marked perforator position. If the trajectory of the perforator deviates more than a specified distance from the marked desired position, the positioning procedure is redone from the present position, considerably reducing the distances the machine has to move, and therefore reducing positioning errors.

Another embodiment of the present invention comprises that said pin holder is slide-able, and that it is provided in different dimensions with different sizes of a central hole for fitting of marking pins and perforators.

In order to be able to accomplish the aims of the present invention two means are part of the invention.

According to the invention a means for marking of directions and holding of tools for perforation in bone structure surgery, for attachment to a machine with a movable arm is set forth. It comprises an outer casing with an aperture for holding an inner casing, one of said casings being slide-able in relation to said movable arm, said inner casing having an attachment for holding perforation means. It is attached to a turnable support or a turnable and tiltable support on said machine.

In one embodiment the slidable casing is electrically actuated to move back and forth.

Another embodiment comprises that one of said casings is revolving for drilling, grinding, milling or other movement used during perforation.

A still further embodiment encompasses that the attachment is able to fit a machine for drilling, grinding, milling or other movement used during perforation.

According to the invention a position determining means used for finding directions for perforation in bone structure surgery, attached to a machine with a movable arm is set forth. It is provided with a first plate and a second plate, both plates being substantially transparent to X-ray radiation in an orthogonal direction, and mounted in an orthogonal configuration, said first plate being provided with four round elements, said second plate being mounted on a turnable and tiltable support for attachment to said machine or initially attached , whereby an X- ray magnification factor relating to two orthogonal X-ray radiographs, comprising the round elements, taken of the bone structure is determined when two of said round elements cover each other in both radiographs, said magnification factor

being determined by the distance between said two uncovered round elements and dependent on the movement of said machine arm.

In one embodiment of the position determining means according to the present invention a turn-able support is mounted on a movable frame of said machine, whereby it can be placed in front of means for marking of directions and holding of tools for perforation on said machine.

In another embodiment of the invention the round elements are opaque to X-ray radiation. The round elements are made out of materials opaque to X-ray radiation such as tantalum, lead, steel etc alloys of said materials.

In a preferred embodiment of the invention said round elements are placed in a square configuration on said first plate.

Brief description of the drawings

For a more complete understanding of the present invention and for further objectives and advantages thereof, reference may now be had to the following description in conjunction with the accompanying drawings, in which:

Fig. 1 schematically illustrates a femoral bone structure in perspective view, indicating symbols for mathematical calculation in accordance with prior art;

Fig. 2 illustrates a cross-section of a dislocated hip fracture showing symbols for fixating means according to the present invention;

Fig. 3 illustrates a cross-section of a non-dislocated hip fracture displaying symbols for fixating means according to the present invention;

Fig. 4 illustrates a femoral bone structure from its anteroposterior projection with marked screw positions according to the present invention;

Fig. 5 illustrates a femoral bone structure from its lateral projection with marked screw positions according to the present invention;

Fig. 6 illustrates a side view elevation of an arrangement according to the present invention;

Fig. 7 illustrates a top plan view of an arrangement according to the present invention;

Fig. 8 illustrates a front view elevation of an arrangement according to the present invention;

Fig. 9 illustrates a flow chart depicting steps taken in a method of the present invention;

Fig. 10 illustrates a side view elevation of a casing with a tool holder on a support according to the present invention;

Fig. 11 illustrates a top plan view of a casing with a tool holder in accordance with Fig. 10;

Fig. 12 illustrates a side view elevation of a casing with a tool holder and support mounted on a robot arm according to the present invention; and

Fig. 13 illustrates a positioning determining means mounted on a support and attached to a robot fundament or stand according to the present invention.

Detailed description of preferred embodiments

In order to accomplish a better determination of where to place fixating means, such as screws, pins, nails etc., on fractured bone parts, the present invention introduces a method specifically developed for the task. The method and arrangements herein disclosed for hip fractures are shown for purposes of illustration only, and are not limiting of the present invention. Hence, the method and means for perforation of bone structures according to the present invention can be used for any bone perforation, not only does related to hip fracture surgery.

The following description taken in conjunction with Fig. 1-9 is subject for a co-pending patent application, and Fig. 10-13 represent the present invention.

With the technique used in the present invention it is possible to achieve an accuracy of ±1.0 mm when attaching fixating screws in hip fracture surgery, and in addition determining the screw length, screw fixating angle, and dislocation degree of the fracture. A method used in connection with the present invention provides means for storing digitized radiographs from performed surgery and patient records in a database for quality checks and scientific research.

In radiographs of femoral neck fractures in accordance with prior art, the position of a pin or screw in relation to a construed femoral neck axis can be determined by measuring the distances from a discretionary point to a construed femoral neck axis, located at the same distance from the femoral head center in both the AP and lateral projections, to the pin or screw. The exact position is obtained if the following criteria are fulfilled:

1. The anterioposterior and lateral radioplates are parallel to the femoral neck axis and perpendicular to each other, and the anterioposterior radioplate is parallel to the femoral shaft axis.

2. The directions of the central X-ray beams in the anterioposterior and lateral projections are perpendicular to the femoral neck axis.

3. The degrees of magnification in the anterioposterior and lateral projections are equal.

A reversed method, i.e., it is determined where to place the pin or screw in the best possible way, is provided in connection with the present invention.

By using an image intensifier to adjust for the position of the femoral neck in space, the criteria nos. 1-3 can be fulfilled. This is time-consuming, however, and impracticable in routine examinations. In routine radiographs of internally fixed femoral neck fractures, the rotation of the hip varies in successive examinations and also in successive exposures, i.e. criteria nos. 1-3 above is not fulfilled. In order to determine the position of where to put pins/screws out off such radiographs, the rotated projections must be derotated to straight anterioposterior (AP) and lateral (Lat) projections. This is intuitively accomplished when a routine radiograph is interpreted, but this derotation is subjective and non-reproducible.

However, by determining the derotation angle omega (Ω) the rotation of the hip can be compensated for in a reproducible way.

A femoral bone structure in perspective view marked up with symbols for mathematical calculation is schematically illustrated in Fig. 1. A method used for determining where fixating means have been placed after a performed surgery in hip fractures, derived from Fig. 1. is prior art, as stated above. Such a method was introduced and used by the inventor of the present invention in his study "Internal Fixation of Femoral Neck Fractures", Stockholm 1993, ISBN 91-628-0804-4. Nevertheless, the method has been used only for post-surgery quality checks and scientific statistics, see "Quality of Reduction and Cortical Screw Support in Femoral Neck Fractures", by Stig Lindequist and Hans Törnkvist, Journal of Orthopaedic Trauma, Vol. 9, No. 3, pp. 215-221, 1995 Raven Press Ltd, New York. A reversed method provided in connection with the present invention can be used in determining how and where to drill in a femoral bone fracture in order to facilitate healing of said fracture in a best possible way.

Despite the fact that the position of the fixation means in femoral neck fractures is considered to be of great importance for the outcome of a performed surgery, no other method of determining this position with a known degree of accuracy has been found in the literature.

It is a known fact that fixating means, as for example screws, are to be placed as adjacent to the femoral neck bone structure (the cortex) 10 as possible, and centered in the femoral head 12 so that a fractured neck 10 can bear relatively heavy loads. Loads of 1500 N is common. This should be considered along with elderly peoples deteriorated content of marrow inside the bone structure, which emphasis the importance of the screws being placed adjacent to the cortex.

"A Simple biplanar method of measuring femoral anteversion and neck-shaft angle" by Ogata K and Goldsand EM, J Bone Joint Surg (Am), 1979, 61:846-51, and "Radiographic measurements of the femoral anteversion, Acta Orthop Scand, 1983; 54: 141-46 by Herrlin and Ekelund, describes how the anteversion angle θ (not shown) and the neck-shaft angle δ can be calculated from the measured cerovicofemoral angles α and β, and the inclination angle ε. According to their methods, the anteversion angle θ is obtained by an assumed derotation of the proximal end of the femur to zero degree of anteversion in the AP and Lat projections. This derotation takes place along the femoral shaft axis 14 and with the lateral radiograph plate positioned along the femoral shaft. However, an assumed derotation of the proximal end of the femur to zero degree of anteversion in the AP and Lat projections can also take place along the femoral neck axis 16. This angle of derotation around the femoral neck axis 16 is defined as Ω. The relation between the rotation angle of the femoral neck Ω, the projected cerovicofemoral angles α and β, the inclination angle ε, the deviation angle κ and the true femoral neck-shaft angle δ can be expressed as follows:

$$\sin \Omega = CD / AC = HI / AC$$
$$= \tan \beta o * (AB + AI)/\tan \delta * AB$$

$\tan \kappa = AI / AD$ and $\tan \alpha = AD/AB$, therefore

$$\sin \Omega = \tan \beta o * (AB + \tan \alpha * \tan \kappa * AB)/\tan \delta * AB$$
$$\sin \Omega = \tan \beta o * (1 + \tan \alpha * \tan \kappa) / \tan \delta$$

$\tan \delta = AC / AB$ and $\cos \Omega = AD / AC$, therefore

$$\tan \Omega = \tan \beta o * \tan \kappa + \tan \beta o / \tan \alpha$$

where κ is the angle of deviation of a central X-ray beam from a direction perpendicular to the femoral neck axis in the lateral projection, and where $\varepsilon = \delta \pm \kappa$

If a derotation by Ω degrees of the femoral neck 10 is assumed to occur, a pin placed along the femoral neck axis will also rotate Ω degrees. If the co-ordinates for the pin position in the digitized radiographs are to be X and Y, a matrix for transformation of co-ordinates in a right-angled co-ordinate system,

$$X' = Y * \sin \Omega + X * \cos \Omega;$$

$$Y' = Y * \cos \Omega$$

will give the corrected co-ordinates X' and Y' for a pin/screw position in the straight AP and Lat projections.

Fig. 1 further illustrates distances and angles **OADG**: Parallel to the film plane 11 in the AP projection 15; **OAEF**: Parallel to the film plane 13 in the lateral projection 17; **OB**: Central axis of the femoral neck 10; **BC**: Central axis of the femoral shaft 18; α: Cervicofemoral angel in the AP projection 15; β: Cervicofemoral angle in the lateral projection 17 when the central X-ray beams are perpendicular to the femoral neck axis 16; βo: Cervico-femoral angle in the lateral projection 17 when the central X-ray beams are not perpendicular to the femoral neck axis 10; ε: The angle of inclination of the central X-ray beams in the lateral projection 17; κ: The angle of deviation of the central X-ray beams in the lateral projection 17 from a direction perpendicular to the femoral neck axis 10; δ: True femoral neck-shaft angles and Ω: Femoral neck rotation angle.

The transformed co-ordinates X´ and Y´ in the femoral head 12 are plotted in a Cartesian co-ordinate system and circumscribed by a circle with the center placed at the origin of the co-ordinate system, and with the radius equal to that of the femoral head 12 at the measuring point. The obtained graph represents a cross-section of the femoral head at the level of the measuring point, as illustrated in Fig. 2 and Fig. 3 described below.

For the femoral neck 10, the transformed co-ordinates X´and Y´are plotted in a co-ordinate system and circumscribed by cross-section graphs of the femoral neck 10.

If series of radiographs are to be compared to each other, all measured distances are converted from mm to units of measurement by dividing the distance by the diameter of the femoral head 12 on the film in question. The values for pin co-ordinates are expressed as fractions of the femoral head diameter.

Provided with the present invention, a known method named PINTRACE ™ has been adapted and developed, to suggest screw positions, in said femoral neck axis 10 and said femoral shaft axis 14 in the AP and Lat radiographs instead of only analyzing already applied screws. The known older method PINTRACE ™ was developed by the same inventor as for the present invention and referred to in his thesis "Internal Fixation of Femoral Neck Fractures", Stockholm 1993, ISBN 91-628-0804-4.

In the original older method PINTRACE ™, the positions of inserted fixating pins/screws are calculated and presented in constructed cross-sections of the femoral neck 10 and head 12. An entirely new PINTRACE 2.0 ™ method was developed. In fact, the common part between the old known PINTRACE ™ and the new PINTRACE 2.0 ™ method is that the configuration according to Fig. 1 is provided in order to make necessary calculations possible. The old PINTRACE ™ method is a sub-method to the method provided together with the present invention where the shape of the femoral neck 10 and head 12 are determined, constructed and displayed on, for example, a computer screen as empty cross-section graphs. This allows a surgeon to place symbols for fixating pins/screws, or use displayed predefined positions for such symbols. It should be appreciated that placing symbols is a dynamic task, which varies among patients, considering the importance of placing pins/screws as adjacent to the cortex as possible. Positions of provided symbols are transferred to the digitized AP and Lat radiographs and overlaid on these in form of colored lines of varying thickness.

To assist a user in detecting incorrect measurements of the femoral neck radii, (PINTRACE 2.0™), according to the present invention, uses a standard neck/head ratio (AP view = 0.70, lateral view = 0.57: "The proximal end of the femur" thesis by Backman, Karolinska Institutet, Stockholm 1957, and "Anatomy of the Femoral Neck and Head with comparative data from Caucasians and Hong Kong Chinese, Hoaglund and Low, Clin.Orthop 152: 10-16, 1980) for a preview calculation of the femoral neck AP and lateral radii. The user can change the calculated standard radii if they differ from the measured radii on the film in question.

Fig. 2 illustrates a cross-section of a dislocated hip fracture displaying symbols for fixating means, here screws indicated by broken lines and filled circles, provided in connection with the present invention.

The cross-section view in Fig. 2 of caput 12 (femoral head) and collum femoris 10 (femoral neck) shows a dislocated hip fracture with two screws attached. Filled black circles 20 represent the position of said screws in collum femoris 10, and filled white circles represent the position of screws in caput 12. Adjacent circles 24, 26 indicate a specific degree of uncertainty for marked up screw positions.

Further, Fig. 3 illustrates a cross section of a non-dislocated hip fracture displaying symbols for fixating means, here screws indicated by broken lines and filled circles, according to the present invention.

The cross-section view in Fig. 3 of caput 12 and collum femoris 10 shows a non-dislocated hip fracture with two screws attached. Filled black circles 20 represent the position of said screws in collum femoris 10, and filled white circles represent the position of screws in caput 12. Adjacent circles 24, 26 indicate a specific degree of uncertainty for marked up screw positions.

Now referring to Fig. 4 and Fig. 5.

Fig. 4 illustrates a femoral bone structure 30 from its anteroposterior projection 15 with two marked screws.

Fig. 5 illustrates a femoral bone structure 30 from its lateral projection 17 with two marked screws 32.

In the AP and Lat radiograph projections 15, 17 the central axes 14, 16 of the femoral neck 10 and shaft 18 are marked and the femoral neck-angles α and β are measured. The distance from the femoral neck axis 16 to a marker which indicates where to position a screw 32, when surgery is performed, at one measuring points in the Lat view 17 is taken to represent the X co-ordinate and the distance in the AP view 15 the Y co-ordinate for the pin. Angles as shown in Fig. 1, Fig. 4 and Fig. 5 are used to place the femoral bone structure 30 in space, thus finally indicating the direction for insertion of screws 32.

Co-ordinates in the inferior or posterior halves of the femoral head 12 and neck 10 are assigned negative values, see Fig. 2 and Fig. 3.

For the femoral neck 10, the point of intersection of the femoral head sphere and the femoral neck axis 16 is used as measuring point. The diameters 34, 35, indicated by

broken lines in figures 4 and 5, of the femoral head 12 and neck 10 are determined at the measuring points in both the AP and Lat projections 15, 17.

Since magnification factors in the AP and Lat projections often differ, all measured distances are adjusted by calculating the ratio of the greatest and the smallest femoral head diameter and then multiplying the distances in the projection with the smallest diameter by the ratio.

A method for determining, in three dimensions, where to position fixating means in a hip fracture by pre-surgery analysis of at least one anteroposterior and one lateral digitized radiograph of said fracture, is provided in connection with the present invention. It comprises the following steps:

determining a construed femoral shaft axis 14 out off said graphs from at least two midpoints on said shaft axis and drawing a line through said midpoints;

determining a construed femoral neck axis 16 from at least two midpoints on said neck axis and drawing a line through said midpoints;

determining femoral neck angles α, β

determining a femoral head diameter 34 out off said graphs by placing a circle over the perimeter of the femoral head 12;

scaling and rotating said radiographs to a predefined size and position, using an angle between the femoral shaft and an Y-axis in said digitized radiographs, and said diameter 34 of the femoral head 12;

determining the distance from said neck axis 16 and the center of said femoral head, representing a remaining displacement of the hip fracture which is implicitly known from said diameter 34;

measuring the height of the medial cortex 19 out off the anteroposterior graph;

displaying said femoral neck angles α, β;

displaying cross-sections (Fig. 2 and Fig. 3) of the femoral head 12 and neck 10 with a predetermined degree of accuracy;

rotating said cross-sections of the femoral head 12 and neck 10 in order to determine a degree of derotation of the hip, imposed by the fracture,

displaying the degree Ω of hip rotation in said anteroposterior and lateral radiographs; and

Also, attached on the robot arm 52 is a tool holder 58, for example, used to hold a drilling-machine.

It is comprised in the present invention that said control box 48 for controlling the robot contains hardware devices, firmware devices and software controlled by a processor, each device known per se, but forming an unique entity for applications according to the present invention. Although, in this preferred embodiment of the invention, only one measurement means is described for performing measurements, it is appreciated that measurement means/function can be composed of multiple means, or integrated into one or more means/function as described below.

Thus, in one preferred embodiment comprising means and/or functions, such as:

measurement means or function accomplishing measurement of the femoral shaft axis 14 out off said graphs from at least two midpoints on said shaft axis, calculating and drawing a line through said midpoints. Further, the device or function measures a construed femoral neck axis 16 from at least two midpoints on said neck axis, 16, calculating and drawing a line through said midpoints. The femoral neck angles α, β are determined. Still further, it measures the height of the cortex 19 out off said anteroposterior graph. Also, the means measures, calculates and determines the femoral head diameter 34 out off said graphs by placing a circle over the perimeter of the femoral head 12, and measures, computes or determines the distance from the femoral neck axis 16 to the center of said femoral head 12, representing a remaining displacement of the fracture, which is implicitly known from said femoral head diameter 34, whereby the means measures, calculates and determines the femoral neck diameter 35 out off said graphs by drawing a line, perpendicular to the femoral neck axis, at the intersection of the femoral head sphere and the central femoral neck axis 16;

a scaling function scaling and rotating said radiographs to a predefined size and position, using an angle between the femoral shaft and an Y-axis in a display, displaying co-ordinate axes together with said digitized radiographs, and said femoral head diameter 34;

a display device for displaying data of interest to hip fracture surgery e.g. digitized radiographs, neck angles α, hip rotation Ω, cross-sections (figures 2 and 3), computed figures, lines 16, 14, etc.

a function providing displays of said cross-sections of said femoral head 12 and femoral neck 10;

a driver for rotating said cross-sections of the femoral head 12 and neck 10 in order to determine a degree of hip derotation between said head and neck, imposed by the fracture; said means

providing control input to a robot with stand means 46 for said robot, tool means on said robot for working in a direction given by said control input, and distortion correcting means (not shown) compensating for x-ray distortion.

Femoral neck angels α,β are displayed by said display as lines and numerical values in said digitized graphs. The lines are automatically re-drawn, preferably controlled through software and/or graphic means, if the value is changed.

Symbols 20 for said fixating means are placed within the cross-section of the femoral neck and displayed by said display.

It is included a device or function that activates a warning function if fixating means 32 are placed outside the femoral neck in said digitized radiographs.

Further, it is included that fixating means for attachment are automatically displayed in said digitized radiographs with relation to made measurements, by software.

Means, such as graphic drivers, can be provided for putting down symbols for fixating means 20, 32 in the digitized radiographs of the present invention.

The method as herein described is preferably applied to control the robot in using its tool to work in the right direction, and prepare for insertion of fixating means such as screws, pins, nails, etc.

The distortion compensating means according to the present invention is described below.

Now referring to Fig. 9, which illustrates a flow chart depicting steps 900 to 980, taken in the method of the present invention, which is applied as control information to an arrangement.

At step 900 AP and Lat radiographs from C-arm fluoroscopy are obtained. The radiographs are digitized, rotated and scaled 910, by drivers for that purpose, followed by performing 920 necessary measurement operations, with means or functions described above, on the radiographs of a hip fracture.

Made measurements are resulting in construction 930, through a software, of femoral neck and head cross-section graphs, which are displayed on a screen. Displayed cross-sections are marked 940 with pin/screw markers, which are changeable through software. An outlining 950 of the marked pin/screw positions in the digitized radiographs is thus performed.

The steps 900-950 are applied to position 960 a robot to drill in said positions. This is followed up by a final check of determined positions. Eventually, during surgery, a surgeon manually inserts 980 pins/screws.

Accordingly it should be understood that the PINTRACE 2.0™ method or like methods are adapted to the method described in accordance with the flow chart.

Henceforth the present invention is described in conjunction with Fig. 10-13. The following description is had to a preferred embodiment of the present invention, but the invention is not limited to this specific embodiment.

Fig. 10 illustrates a side view elevation of a casing with a tool holder on a support according to the present invention; and

Fig. 11 illustrates a top plan view of a casing with a tool holder in accordance with Fig. 10.

The arrangement 100 with a tool holder or drill guide system as depicted in Fig. 10 and 11 comprises a support 110 to be mounted on a machine 40, like a robot with an articulated arm 52. It further comprises a means of attachment 112 for support 110 and an outer casing 114 with a slide-able inner casing 116 acting as a so called end effector holder or tool holder with a stop screw 118 for locking of the inner casing 114. A flanch 120, for forming of a stop position for the inner casing, is provided. Finally an X-ray marker pin 122 is hold by the inner casing. The marker 122 can as well be changed to another end effector such as a tool, for example, a tool for drilling, screwing, pinning, milling, grinding, threading etc, or even machines for the same purposes could be attached to the inner casing 116.

In a preferred embodiment, the support 112 is turnable and lock-able (not shown).

Now referring to Fig. 12 which illustrates the arrangement according to Fig. 10 and 11 attached to an articulated robot-arm 52. The arrangement comprises the same components as in the two previous figures and a sliding arrangement 200 with upper 124 and lower 126 slide-able plates. The lower slide-able plate 126 is attached to an electrically isolating plate 128, and working flanch 130 (platform 130) articulated attached to the robot-arm 52.

Sliding plates 124, 126 mounted on a robots working flanch 130 makes it possible to move a part of the arrangement 100, manually or by electric means in a forward - backward direction. An electronic distance measuring apparatus is attached to the sliding

arrangement 200 and provides input to the robot about the distances the sliding device has moved.

The casing 114 is possibly a metallic cylinder and attached to the support 112. Another casing 116 formed as a metallic cylinder fits into the first cylinder 114. It is provided with a central hole through which pins or drills can be introduced. The inner cylinder 116 is available with different diameters of the central hole through which different end effectors such as drills, screws, pins etc can be introduced.

A small steel pin 122 with radiographic markings for each 25 mm at one end is introduced through the central hole and serves as a measurement guide.

Also depicted in Fig. 12 is a sterilized cloth 132 for anti bacterial protection during preparations for surgery.

Now referring to Fig. 13 which shows a positioning determining arrangement 140 mounted on a support 150 and attached to a support connected to the robot fundament or stand 42 according to the present invention.

X-ray distortion is compensated for with a new inventive method and an arrangement 140, 150 for that purpose.

X-ray distortion such as magnification arises from a diverging X-ray beam as it is emitted from an X-ray tube towards a radioplate. Hence by having a reference at a predetermined distance from the tube a magnification factor would be gained by the ratio of the distance measured on a radioplate with the known distance of the reference.

The arrangement comprises, in a preferred embodiment, a plexiglass plate 152 with four lead balls 154 attached and placed in a square pattern. While trans-illuminating in the AP and Lat projections in parallel with the ball pattern, two balls 154 are adjusted to be placed in the center of the radiation field so that they cover each other entirely. Thus, through measuring the distance between the two balls that are uncovered, an absolute measure of the distortion is determined (the magnification ratio) provided that a predetermined distance between the radiation tube and the plexiglass 152 plate is upheld. This distance corresponds to the working distance when distance determinations are made. A calculation in percentage to adjust the robot arm is finally applied.

Depicted in Fig. 13 is an open plexiglass box 140 with two plates 154, 156 attached orthogonal to each other. Plate 154, in a vertical position in Fig. 13, provided with four X-ray opaque balls in a square pattern. The plates 154, 156 are mounted on a support 150, which is attached to a fundament 42 for the robot. Four means of attachment are making up the support

150. A first means 158, here a rod, is mounted on a frame 160 of the robot fundament 42, which is movable back and forth in relation to the frame 160. A second means 162 is movable around the rod 158, and attached to the rod 158. A third means 164 is attached to an axis 166 which makes it movable in a vertical direction to said means 164. Finally, the fourth means 168 is movable in relation to said third means 164 horizontal and slide-able in all directions possibly in 360 degrees if neccessary.

Said plates 152, 156 are of a material substantially transparent to X-ray radiation and provided with 4 round elements in a square configuration. The round elements are made of X-ray opaque material such as tantalum, lead, steal etc. The support 150 is movable in three dimensions so it can be placed in front of robot 40 end effector and, after measuring, retracted so it does not disturbe the movement of a robot arm 52.

Specific steps 1)-3) are provided for control of position determining etc in accordance with the present invention, seth forth below:

1) A computer program designed to calculate the magnification factor from measurements on the measuring template (position determining arrangement).

2) A computer program designed to calculate the desired movement of the robot arm from input measurements through i) the position of the Alignment system, ii) the position of the Marking pin and iii) the marked position for the drill / screw / pin in the bone.

3) A computer program for checking the final robot position.

Henceforth, a method used in the present invention is described.

A) Activate the robot arm and move to a defined start position with, for example for drilling, the arrangement for marking 100 pointing forward and the marking pin 122 put in place and extending, for example, 50mm. The robot is assigned a first start tool Position, i.e. the robot adapts its co-ordinate system so that each movement is carried out around the tip of the marking pin 122. Said measuring template 140 is placed in front of the drill guide 100. Place the measuring template vertical to the floor and adjust it so that the marking pin 122 hits each round element 154 when the robot moves a specified distance in a square pattern.

B) Placing of the measuring template 140 adjacent to the part of a body where the drilling / screwing is intended. A movable X-ray machine (C-arm) is placed and adjusted so that, when radiographs are taken, two out of the four round elements 154 cover

each other in the two orthogonal planes (AP and Lat projection). The position for the two covered round elements represent a starting position for the robot. Said two radiographs are digitized and fed into a computer and the distances between the two uncovered round elements, representing the magnification factor, is calculated and displayed by a computer program. The magnification factor relates to the movement of the robot arm.

C) Said thin steel-pin 122 (the marking pin) with radiographic markings for 25 mm on one end introduced through the central hole in the second cylinder so it protrudes 50 mm. By advancing the sliding arrangement 200 the marking pin 122 penetrates through the skin and muscles to a position close to the bone which is to be drilled. Distances the sliding device has to move are measured manually or electronically and fed into a robot 40 computer program. Now providing the robot a second tool position, start tool position two, according to the distance the sliding device has moved. Now letting the arm 52 move around this second position even if the pin and second cylinder is removed, meaning that all robot movements can take place outside the patients body, but the center of movements will still be close to the bone inside the patients body.

D) Two radiographs (AP and Lat) are taken and digitized, and fed into a computer. The position of the marking steel pin 122, and the length of the 25 mm marking, are measured on the digitized radiographs. A scale factor for this position is calculated.

E) A desired position for the drill / pin / screw in the bone is marked on the digitized radiographs. The computer program now compares the desired position for the drill / pin / screw in the bone with the actual position for the marking pin. After making corrections for magnification (B) and Scale (D) the computer calculates the distances and angles the robot has to move in order to align the marking pin with the desired drill / pin / screw position in the bone. These distances and angles are fed into the robot computer and the robot repositions itself accordingly.

F) After the robot 40 has moved into the new position, the marking pin 122 and the second cylinder 116 is changed to similar devices, suitable for drilling, screwing, pinning etc. A chosen end effector is advanced by means of the sliding arrangement 200 so that it enters through the skin and muscles to a position close to the bone. At this, AP and Lat radiographs are taken and digitized. A computer program performs a checking procedure by marking and outlining the direction and position of the end effector (pin/screw/drill) and comparing it with the marked desired pin/screw drill position. If the

trajectory of the end effector deviates more than a specified distance from the marked desired position, the positioning procedure is redone from the present position. This will considerably reduce the distances the robot has to move and therefore reduce the positioning errors.

G) When the end effector is optimally positioned, the surgeon manually introduces pins/screws or drills through second cylinders 116 with central holes in different sizes. A drilling machine can also be fixed to the sliding device and automatically introduce the end effectors. To ensure stability and safety, the robot arm is locked during drilling procedures, thus creating a stable platform for these procedures.

It is thus believed that the operation and construction of the present invention will be apparent from the foregoing description. While the method and arrangements shown or described have been characterized as being preferred, it will be obvious that various changes and modifications may be made therein without departing from the spirit and scope of the invention as defined in the following claims.

———

Claims

1. A method for aligning an arrangement (100, 200) for marking of directions for perforating together with a position determining arrangement (140, 150), attached to a machine (40) with a movable arm (52), in bone structures at surgery, **characterized** in that it comprises the following steps:

attaching a marking pin (122) to said arrangement (100, 200) for marking;

activating said machine (40) and move said arrangement for marking to a defined start position;

assigning said machine (40) a first operation position changing its co-ordinate system so that movement of the marking pin (122) is, approximately, performed within the cross-section of a movable marking pin holder (114, 116);

aligning said position determining arrangement (140, 150) in relation to said arrangement for marking (100, 200), said position determining arrangement having at least four round elements (154);

positioning said position determining arrangement (140, 150) vertical to a reference surface, adjusted so that the marking pin (122) points in a direction, which axis coincides with each round element (154) when the machine moves a specified distance in a square pattern;

placing said position determining arrangement (140, 150) adjacent to the part of a body where the perforation is to be made;

placing an X-ray machine adjusted so that, when radiographs are taken, two of said four round elements (154) cover each other in two orthogonal projection planes;

determining a starting position, whereby said two covered round elements (154) represent the starting position for the machine (40);

digitizing said radiographs and using the distances between said other non covered round elements in said radiographs, representing the magnification factor, which is determined and displayed, whereby the magnification factor relates to the movement of the machine arm (52);

introducing said marking pin (122) through skin and muscles to a position close to the bone structure (30) which is to be perforated;

measuring the distance the marking pin holder (114, 116) has to be moved, thereby giving the machine (40) a second operation position in accordance with the distance

the marking pin holder has been moved, whereby the machine arm (52) is able to move around this second position even if the pin and second cylinder (116) is removed, thus all machine movements can take place outside a patients body, but the center of movements will still be close to the bone inside the patients body;

measuring the position of the Marking steel pin, and the lenght to a predetermined marker on said marking pin (122) out off said digitized radiographs, calculating a scale factor for the position of the marker;

marking a desired position for a perforation arrangement in the bone on said digitized radiographs;

comparing a desired position for said perforation arrangement in the bone with the actual position for said marking pin (122);

making corrections for magnification and scale;

calculating distances and angles that said machine has to move its arm in order to align the marking pin with the perforation position in the bone;

automatic repositioning of the machine (40) in accordance with said calculated distances and angles; and

through said machine, performing a perforation of the bone.

2. A method according to claim 1, **characterized** in that the marking pin is changed to a perforator, hold by a similar pin holder, said perforator being suitable for drilling, screwing, pinning, milling, grinding or threading.

3. A method according to claims 1 or 2, **characterized** in that a chosen perforator is advanced, by means of said pin holder (114, 116) in said arrangement (100, 200), so that it enters through the skin and muscles to a position close to the bone.

4. A method according to claims 1-3, **characterized** in that a checking procedure is performed by marking and outlining the direction and position of the perforator and comparing it with the marked perforator position, thus if the trajectory of the perforator deviates more than a specified distance from the marked desired position, the positioning procedure is redone from the present position, considerably reducing the distances the machine (40) has to move, and therefore reducing positioning errors.

5. A method according to claims 1-4, **characterized** in that said pin holder (114, 116) in said arrangement (100, 200) is slide-able, and that it is provided in different

dimensions with different sizes of a central hole for fitting of marking pins (122) and perforators.

6. An arrangement (100, 200) for marking of directions and holding of tools for perforation in bone structure surgery, for attachment to a machine (40) with a movable arm (52), **characterized** in that it comprises an outer casing (114) with an aperture for holding an inner casing (116), one of said casings (116) being slide-able in relation to said movable arm (52), said inner casing (116) having an attachment for holding a perforation arrangement.

7. An arrangement according to claim 6, **characterized** in that it is attached to a turnable support (112), or a turnable and tiltable support on said machine.

8. An arrangement according to claims 6 or 7, **characterized** in that said slidable casing (116) is electrically actuated to move back and forth.

9. An arrangement according to claim 6-8, **characterized** in that one of said casings (116) is turnable for drilling, grinding, milling or other movement used during perforation.

10. An arrangement according to claims 6-8, **characterized** in that said attachment is able to fit a machine for drilling, grinding, milling or other movement used during perforation.

11. A position determining arrangement (140, 150) used for finding directions for perforation in bone structure surgery, attached to a machine (40) with a movable arm (52), **characterized** in that it is provided with a first plate (152) and a second plate (156), both plates being substantially transparent to X-ray radiation in an orthogonal direction, and mounted in an orthogonal configuration, said first plate (152) being provided with four round elements (154), said second plate (156) being mounted on a turnable and tiltable support (160, 162,164) for attachment to said machine (40) or initially attached , whereby an X- ray magnification factor relating to two orthogonal X-ray radiographs, comprising the round elements (154), taken of the bone structure is determined when two of said round elements cover each other in both radiographs, said magnification factor being determined by the distance between said two uncovered round elements and dependent on the movement of said machine arm.

12. An arrangement according to claim 11, **characterized** in that said turn-able support is mounted on a movable frame of said machine, whereby it can be placed in front

of an arrangement (100, 200) for marking of directions and holding of tools for perforation on said machine.

13. An arrangement according to claims 11 or 12, **characterized** in that said round elements (154) are opaque to X-ray radiation.

14. An arrangement according to claim 13, **characterized** in that said round elements (154) are made out of materials opaque to X-ray radiation such as tantalum, lead, steel etc alloys of said materials.

15. An arrangement according to claims 11-14, **characterized** in that said round elements are placed in a square configuration on said first plate.

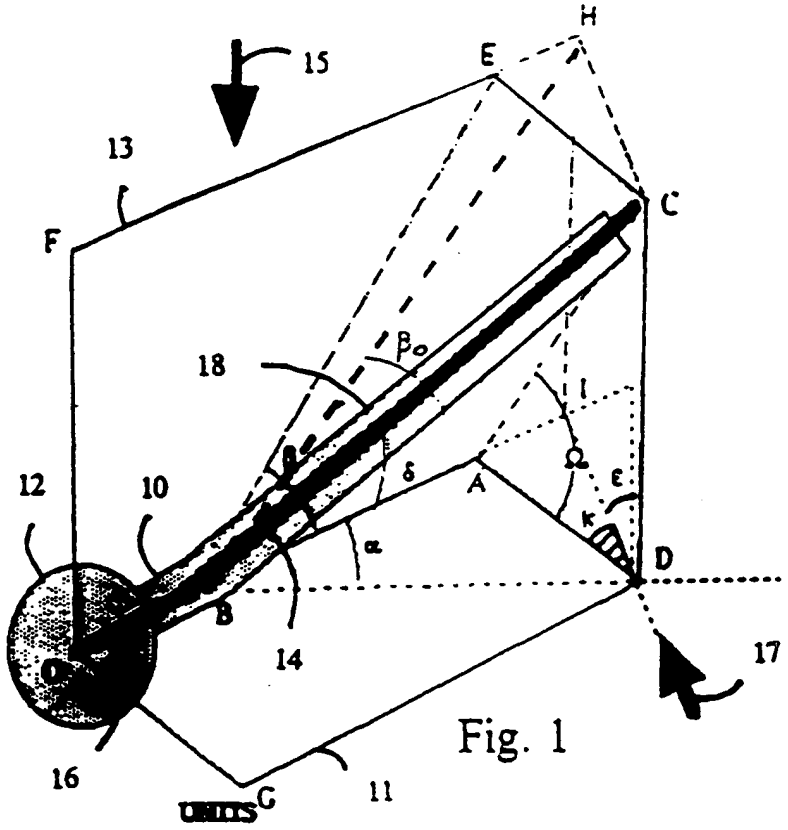
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Fig. 1

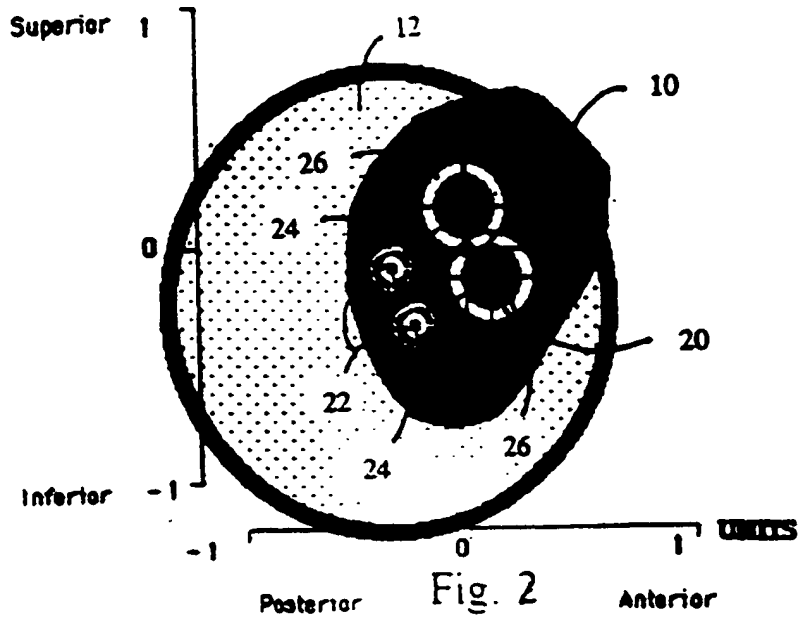
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Fig. 2

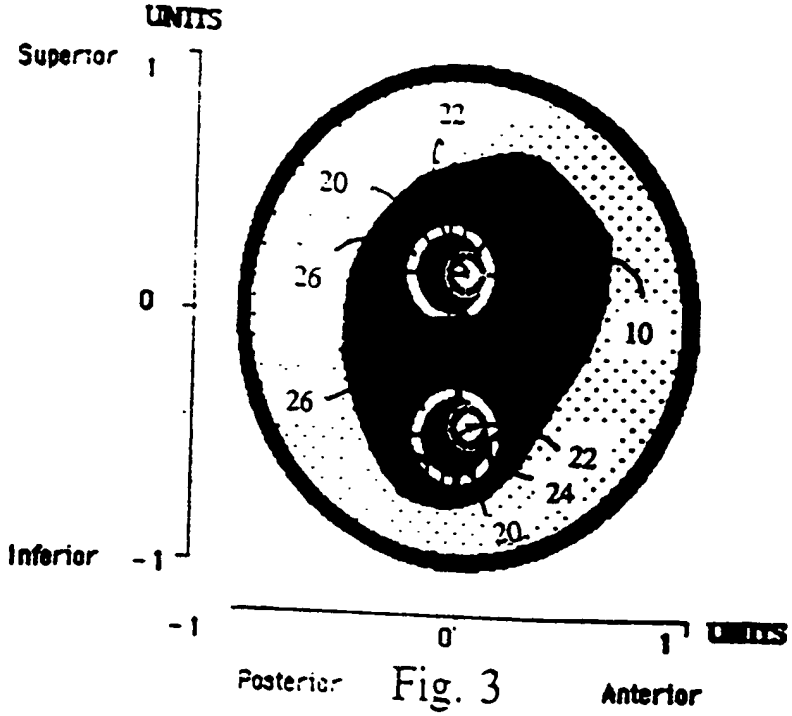
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Fig. 3

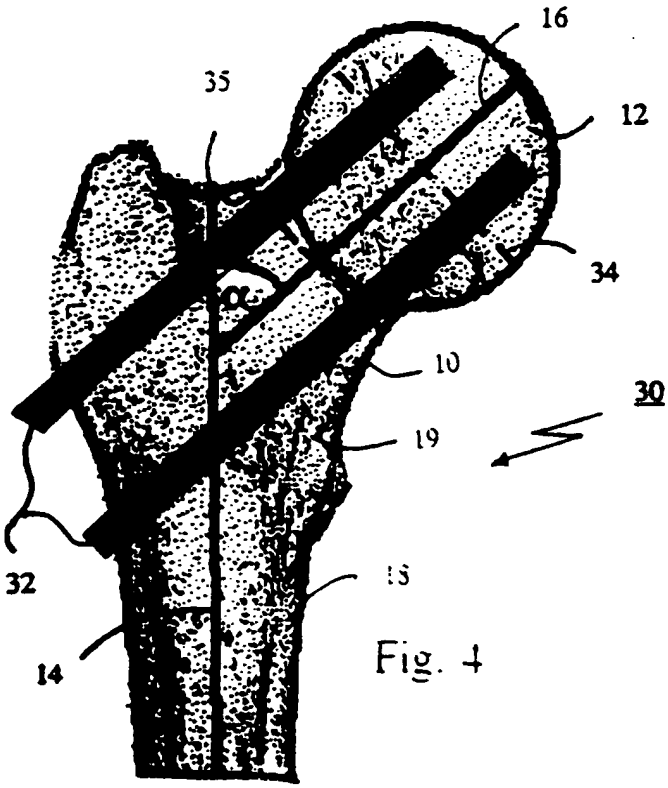
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Fig. 4

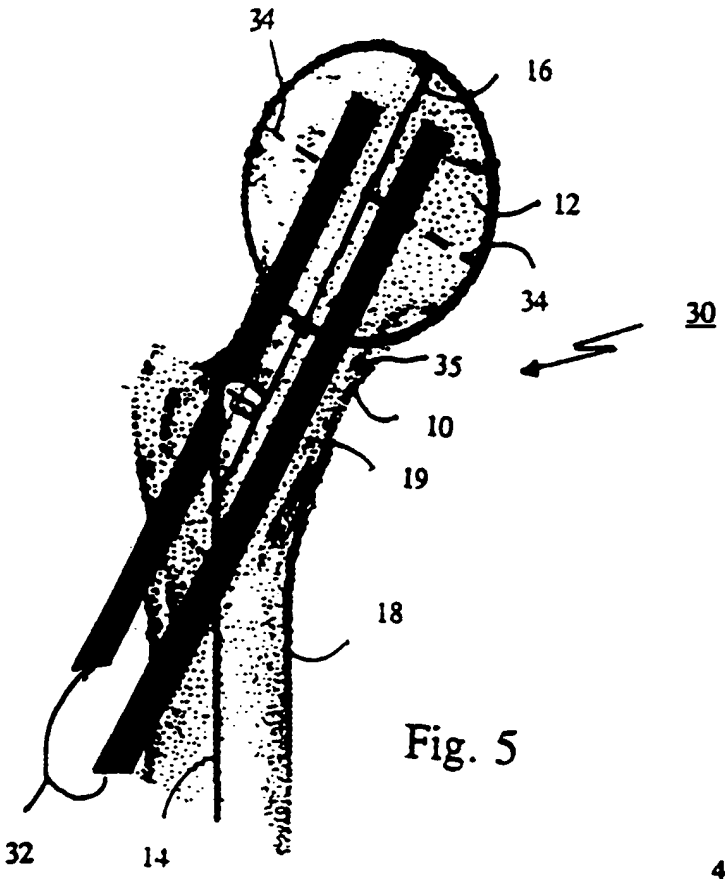

Fig. 5

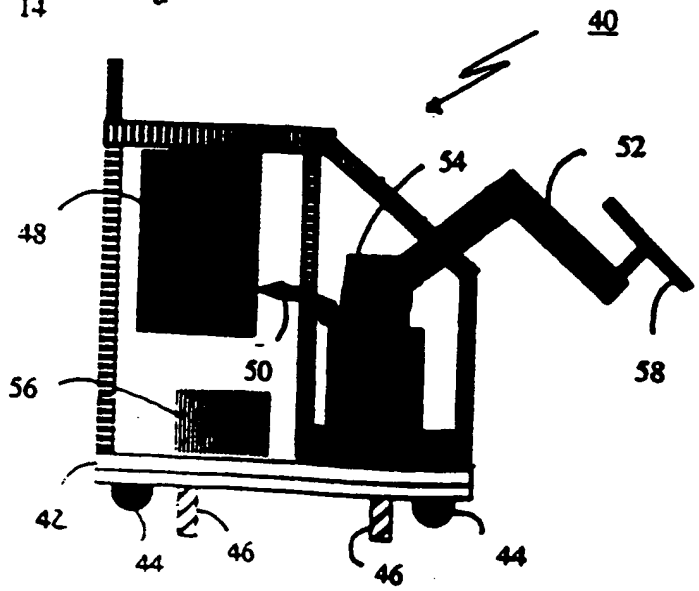

Fig. 6

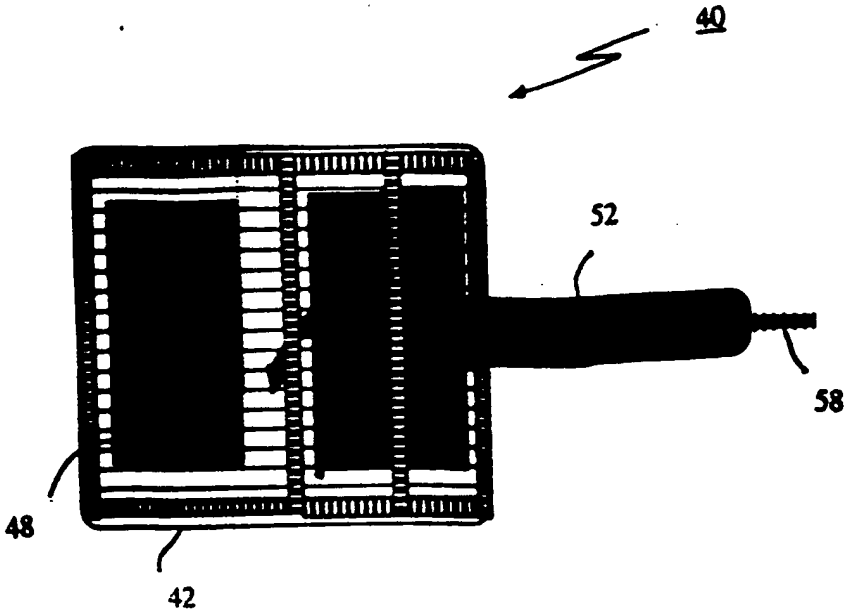

Fig. 7

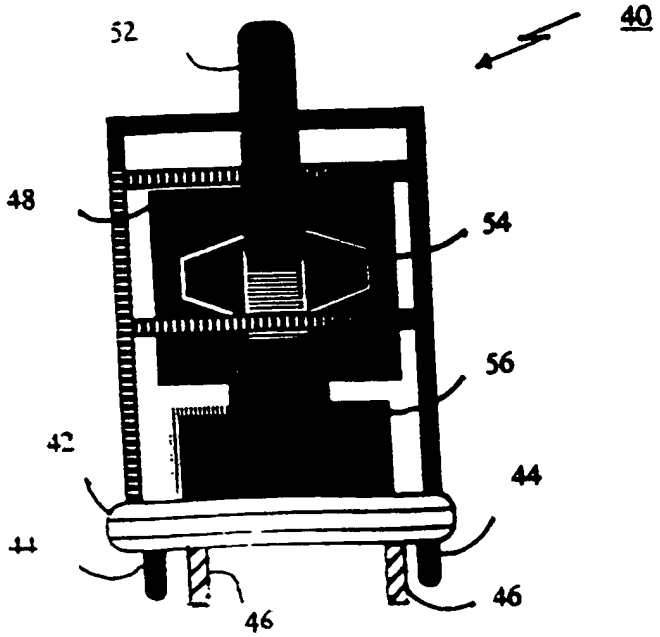

Fig 8

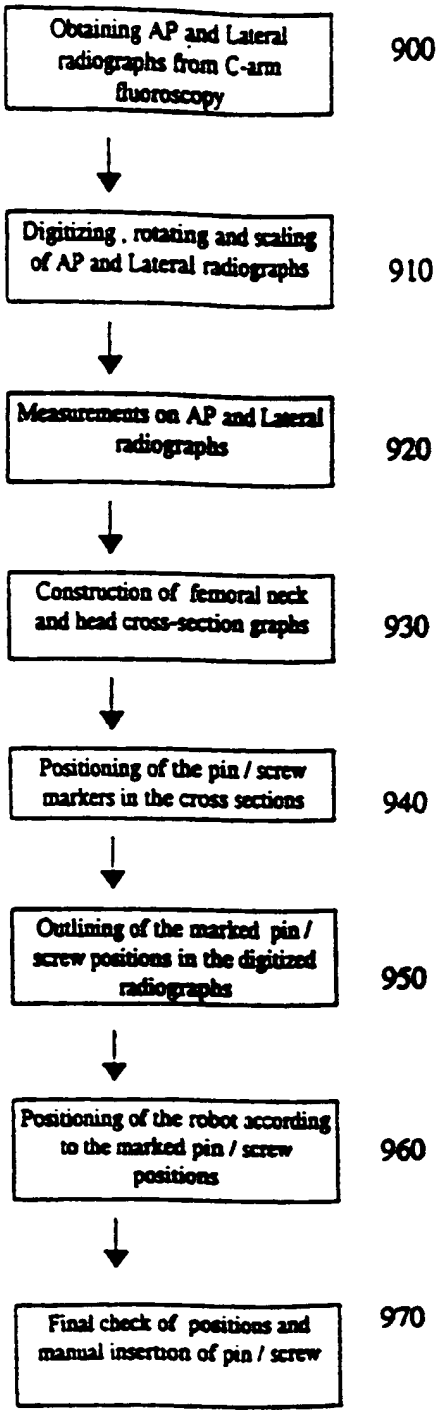
Obtaining AP and Lateral radiographs from C-arm fluoroscopy
900
Digitizing , rotating and scaling of AP and Lateral radiographs
910
Measurements on AP and Lateral radiographs
920
Construction of femoral neck and head cross-section graphs
930
Positioning of the pin / screw markers in the cross sections
940
Outlining of the marked pin / screw positions in the digitized radiographs
950
Positioning of the robot according to the marked pin / screw positions
960
Final check of positions and manual insertion of pin / screw
970

Fig. 9

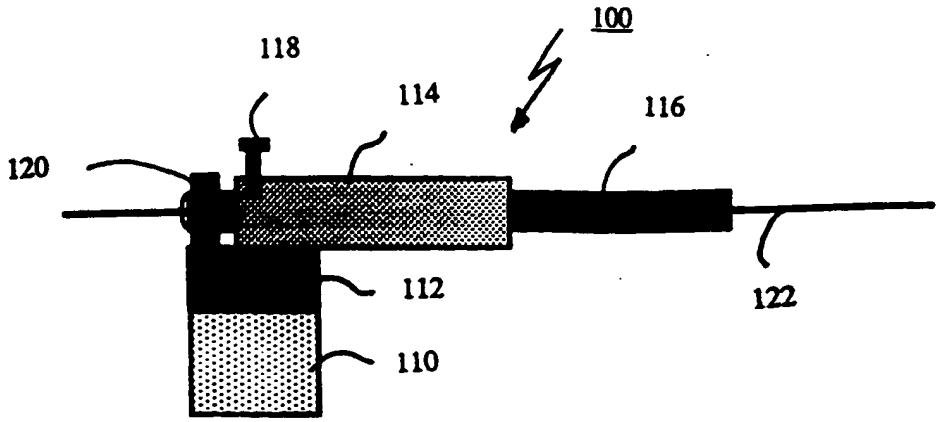

Fig. 10

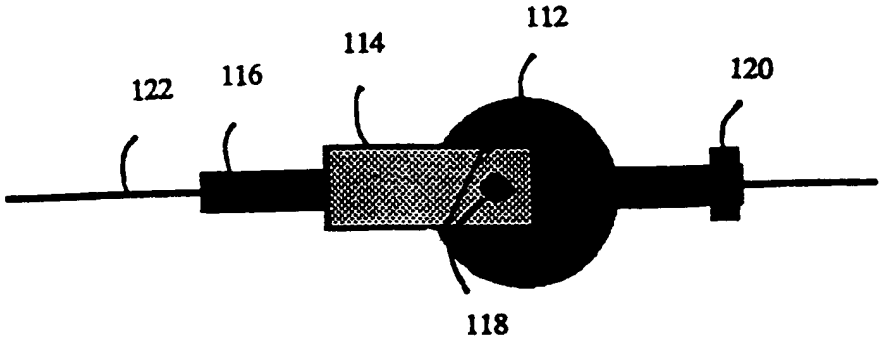

Fig. 11

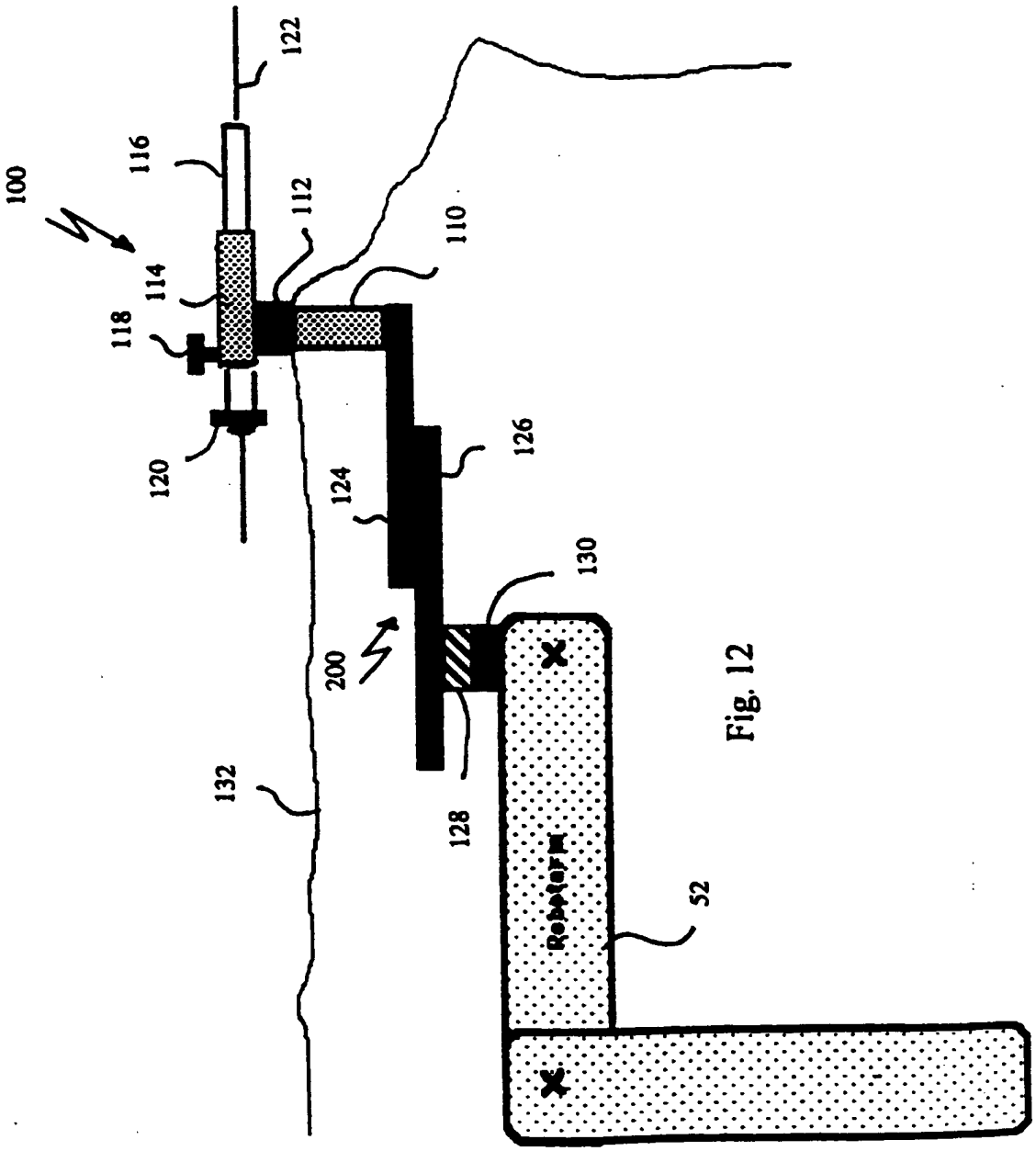

Fig. 12

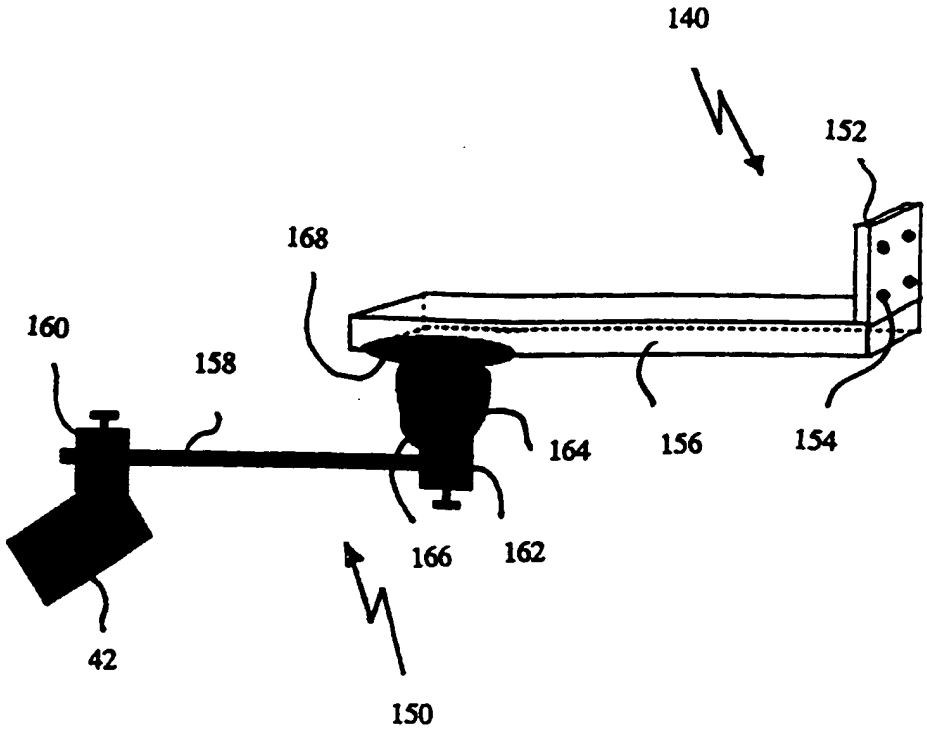

Fig. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99/00521

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 6/00, A61B 17/88, A61B 17/16
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	First International Joint Conference Computer Vision, Virtual Reality and Robotics in Medicine and Medical Robotics and Computer-Assisted Surgery Grenoble, France, March 19-22, 1997, Jocelyn Troccaz et al:"CVRMed-MRCAS'97", pages 567-569 --	6-15
X	US 5569256 A (W.J. VAUGHN ET AL.), 29 October 1996 (29.10.96), column 1, line 63 - column 3, line 9, abstract -- --------	6-10

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 July 1999	09 -08- 1999
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Lotta Gunnarsson Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99/00521

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-5
because they relate to subject matter not required to be searched by this Authority, namely:

Surgical method, see Article 17(2)(a)(i) and Rule 39.1(iv).

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1) Claim 6-10. Holder for a tool which perforates bone.

2) Claim 11-15. Device for controlling where to perforate the bone.

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [X] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/07/99

International application No.
PCT/SE 99/00521

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5569256 A	29/10/96	NONE	